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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/871,125	05/31/2001	Michael W. Pariza	960296.97958	2562

7590 11/19/2002

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EXAMINER
HUI, SAN MING R

ART UNIT	PAPER NUMBER
1617	9

DATE MAILED: 11/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/871,125	PARIZA ET AL.	
	Examiner	Art Unit	
	San-ming Hui	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 August 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-47* is/are pending in the application.

4a) Of the above claim(s) *9,15-17 and 19-47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,10-14 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The response filed August 27, 2002 is acknowledged.

Claims 1-47 are pending. As stated in the previous office action mailed May 21, 2002, claims 15-16 and 20-47 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected invention. Furthermore, claims 9, 17, and 19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected species.

Claims 1-8,10-14, and 18 are examined on the merits herein to the extent they read on the elected invention and species.

This application contains claims 15-16 and 20-47 are drawn to an invention nonelected with traverse in Paper No. 6. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Response to Applicant's remarks on Election/Restriction

Applicant's remarks regarding claims 15 and 16, which are drawn to reducing the lipoxygenase level, being different from inhibiting the enzyme have been considered, but are not found persuasive. Reducing the level of an enzyme, such as lipoxygenase, and inhibiting the same enzyme involve different medical technologies. Reducing the level of an enzyme requires the inhibition of the expression of such enzyme (usually by gene manipulation so that the cells will not express the enzyme), resulting in the decrease of the serum concentration or amount of the enzyme. However, the inhibition

of the enzyme involves compounds or agents to "block" the activity of the enzymes, even when the level of the enzymes is not reduced. The search fields involving these two inventions are separate, distinct, and divergent. The restriction requirement set forth in the previous office action mailed May 21, 2002 is therefore, deemed proper and final.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8,10-14, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khandwala et al. (US Patent 5,827,898 from the Information Disclosure Statement received October 5, 2001), Park et al. (Lipids, 1999; 34(3): 235-241 from the Information Disclosure Statement received October 5, 2001).

Khandwala et al. teaches NDGA is known to be useful in reducing cholesterol and triglyceride level (note: reducing fat in the body)(See particularly col. 3, line 23-35). Khandwala et al. also teaches 350mg/kg of NDGA daily is useful in reducing body weight in mice (See col. 11, line 34 - col. 15; particularly Table 1-2).

Park et al. teaches *trans*-10,*cis*-12-conjugated linoleic acid is known in reducing body fat in mice (See particularly the abstract). Park et al. also teaches the amount of

trans-10,*cis*-12-conjugated linoleic acid in the mice diet is around 0.25% (See particularly page 237, col. 1, fourth paragraph).

The references do not expressly teach the two agents are used together in the method of controlling body fat. The references do not expressly teach the amount of NDGA employed herein.

It would have been obvious to one skill in the art when the invention was made to employ NDGA and *trans*-10,*cis*-12-conjugated linoleic acid in the herein claimed amount in a method of controlling body fat.

One of ordinary skill in the art would have been motivated to employ NDGA and *trans*-10,*cis*-12-conjugated linoleic acid in the herein claimed amount in a method of controlling body fat because both NDGA and *trans*-10,*cis*-12-conjugated linoleic acid are known to be useful for controlling body fat (reducing body fat). Therefore, combining two agents which are known to be useful to reducing body fat individually into a method useful for the very same purpose is *prima facie* obvious. See *In re Kerkhoven* 205 USPQ 1069. In addition, the optimization of therapeutic effect parameters (dosage range, dosing regimens) is obvious, as being within the skill of the artisan.

It is applicant's burden to demonstrate unexpected results over the prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and

be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972). In the instant case, examples disclosed in the instant specification, pages 8-14, have been considered, but are not found persuasive. The data merely demonstrates the efficacy of NDGA, the elected compound, in reducing body fat (See Table 4 in page 11). However, this is seen to be an expected effect based on the cited prior art. No convincing and clear unexpected result is seen.

Response to Arguments

Applicant's arguments averring the specific mechanism of action of NDGA filed August 27, 2002 have been fully considered but they are not persuasive. Firstly, the cited prior art clearly teaches that NDGA is effective in reducing body fat (See Khandwala et al.). Secondly, the mechanism of action of NDGA does not lend any patentable weight to the herein claimed method of controlling fat in the body by administration of NDGA. Please note products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada* 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

Applicant's arguments averring the reduction in weight is not necessarily related in any way to a reduction in body fat have been considered, but are not found persuasive. Khandwala et al. clearly teaches that NDGA is effective in reducing body

fat (NDGA is effective in reducing triglycerides). It is well-known in the art that body stores fat as triglycerides or triacylglycerols (See Voet and Voet, Biochemistry, published by John Wiley & Sons, 1990, page 271-274, especially page 274). One of ordinary skill in the art would be charged to have possession of a basic biochemistry textbook such as Voet and Voet. In view of the teachings of the cited prior art, reducing triglycerides would be reasonably expected to reduce body fat, absent evidence to the contrary.

Applicant's arguments averring there is no Table 12 in Khandwala et al. have been considered, but are not found persuasive. Examiner apologizes the oversight in the previous office action mailed May 21, 2002. However, there is only four tables disclosed in Khandwala et al., and only Table 1 and 2 related to the elected compound, NDGA. As discussed above, Khandwala et al. teaches NDGA is known to be useful in reducing cholesterol and triglyceride level as well as reducing body weight in mice (See col. 3, line 23-35; also col. 11, line 34 - col. 15; particularly Table 1-2). Therefore, possessing the teachings of the cited prior art, one of ordinary skill in the art would reasonable expect the administration NDGA be useful as reducing body fat, absent evidence to the contrary.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (703) 305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui
November 13, 2002

SREENI PADMANABHAN
PRIMARY EXAMINER

11/18/02